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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|----------------------|
| 09/852,455 | 05/09/2001 | Arthur J. Blume | 2598-4004US1 | 5124 |
| 27123 | 7590 | 09/12/2005 | | EXAMINER |
| MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101 | | | | WESSENDORF, TERESA D |
| | | | ART UNIT | PAPER NUMBER |
| | | | | 1639 |

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/852,455 | BLUME ET AL. |
| | Examiner | Art Unit |
| | T. D. Wessendorf | 1639 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 16 June 2005.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-56 is/are pending in the application.

4a) Of the above claim(s) 2-3, 13-14 and 17-56 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,4-12,15 and 16 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-56 are pending in the application.

Claims 2-3, 13-14 and 17-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species.

Claims 1, 4-12 and 15-16 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, first paragraph

Claims 1, 4-12 and 15-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons advanced in the last Office action, 3/23/04 and 12/22/2004.

Response to Arguments

The applicants assert that the term binding partner precursor is adequately described and that a structural description is neither required nor possible in this case. As exemplified in independent claim 1, the present invention is

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directed to a method of identifying a binding partner or binding partner precursor. The applicants emphasize that claim 1 is directed to a method of identifying the binding partner and not to a composition comprising the binding partner or it's precursor. The identification of the binding partner or it's precursor is a result of the method not a limitation of the claim and as such paragraph 1 of 35 U.S.C. 112 does not require a structural description. Further, since the method is directed to identifying the binding partner and the method is applicable to identifying a broad range of potential binding partners the applicants can hardly be required to provide a structural description of a substance that is not yet identified.

In reply, to be entitled to such weight in method claim, the recited structural limitations therein must affect the method in a manipulative sense and not amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 782 O.G. 639, 135 USPQ 31 (1961). If the binding partner or precursor is the result of the method then, how can this result be achieved when the sequence to which this binding partner is supposed to attach is not also given? The structure of the binding partner being sought need not recite a structure. However, the library from which the amino acid motif that binds

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to said partner or precursor should recite an amino acid sequence for binding to happen. The claims recite for too numerous undefined variables that raise a question whether applicants are indeed in possession of the huge scope of the claimed genus. The broad method recites only two steps. None of the components of the broad method recites any structure or distinguishing characteristics.

To satisfy a written description requirement for a claimed genus a sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406. A representative number of species means that the species, which are adequately described, are representative of the entire genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure indicates that the applicants have invented species sufficient to constitute the gen[us]. Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d

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1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004). See also

University of Rochester v. G.D. Searle & Co., 68 USPQ2d 1424 (DC WNY 2003).

Claim Rejections - 35 USC § 102

Claims 1, 4-5, 9-12 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ivanenkov et al (The Journal of Biological Chemistry, 6/16/95) for reasons set forth in the last Office action, 12/22/2004.

Response to Arguments

The applicants would point to page 14653 at the bottom of the second column and continuing to page 14654 where the statement "....no proteins demonstrated complete identity with our S-100b binding peptide isolates. . ." is made and a list of 3 additional criteria that were used to select the binding partners is given. In addition it is also stated that they need to restrict, at least initially, other focus to identification of peptides contained within molecules known to participate in regulating cytoskeletal interactions." These steps are not required or claimed in the present invention and the applicants therefore assert that the present invention, as claimed, is a patentably distinct improvement over Ivanenkov because the present invention identifies naturally occurring binding partners using fewer steps.

In response, there is nothing in the claims to preclude the steps argued by applicants. Furthermore, as stated by applicants complete identity is not made however, identity to the select binding partners is made. The claims do not recite for any structure to preclude the incomplete identity made by Ivanenkov. As stated in the last Office action, Ivanenkov discloses at page 14653, paragraph bridging col. 1 and col. 2 up to page 14654, that in addition to aligning sequences of individual S-100b binding peptides with each other, naturally occurring proteins possessing sequences similar to the obtained consensus motif of S-100b binding peptides were determined. Such determination was done by comparing the binding peptide isolates (Table 1) with structures in GenBank using BLAST. Several modifications (reads also on the claimed precursor) were applied that identifies the natural protein actin capping protein ACP, CapZ (Table II). The claimed precursor will also read on Ivanenkov's description of proteolytic fragmentation of various S-100 target proteins, isolation and characterization of S-100 binding peptides from these proteolytic soups might permit the identification of consensus S-100 binding epitopes within the different S-100 targets (page 14652, col. 1).

Claims 1, 4-5, 9-12 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kraft (The Journal of Biological Chemistry, 1/22/1999) for reasons advanced in the last Office action, 12/22/2004. [This rejection was based on the natural proteins and not to its precursor.]

Response to Arguments

In the case of Kraft, we have previously argued in our May 29, 2003 and September 23, 2004 responses that this reference does not disclose a method of identifying a naturally occurring binding partner.

In reply, the responses to applicants arguments of May 29, 2003 and September 23, 2004 is incorporated herein and reiterated below:

Kraft clearly states that this is a naturally occurring binding partner as the motif is obtained from a natural binding protein. Kraft states that the biological relevance of such homology of $\alpha\beta_6$ is not known. However, the peptide binding effect is known to be inhibitory of the natural ligand (from which the peptide was obtained that inhibits binding to its natural partner). Kraft discloses that it is the homologous relevance of the different non-previously unidentified compounds that do not have a biological significance i.e., a further identification of the other substances that can bind to the

motif. However, the motif itself is known to bind to a naturally occurring partner in addition to the found homologous compounds. Kraft states "...FASTA search of the GEMBL databases revealed several-extracellular matrix components related consensus sequences...including fibrinogen...With the exception of tenascin, which has been reported to bind in an RGD-dependent way to... $\alpha v\beta 6$, none of these molecules has been implicated previously as a ligand for $\alpha v\beta 6$, thus, the possible biological relevance of such homologies remains unknown...". (Emphasis added.) [It is of interest to note that the claims simply recite that the gene product identified as the naturally occurring binds to a partner. It does not equate such binding to a biological significance especially for the non-structured compound as instantly claimed.]

Claim Rejections - 35 USC § 103

Claims 1, 4-12 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivanenkov in view of Kay et al (6,303,574) for reasons of record, 12/22/2004.

Response to Arguments

Applicants argue that in order to establish a prima facia case of obviousness there must be a motivation to combine the

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references, In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1993). Kay is cited by the Examiner as teaching the use of a random sequence of 9-45 amino acid residues encompassing a consensus sequence in order to improve the binding selectivity's or specificities. Ivanenkov discloses in Table 1 that 80% of the unique sequences had a common motif of 8 amino acids, there is no disclosure that additional amino acids are needed. Therefore one of ordinary skill in the art would have no motivation to combine Ivanenkov with Kay to produce a longer length random peptide chain ⁱⁿ _A order to locate and fingerprint the motif with high specificity and selectivity.

In response, attention is drawn to the abstract at page 14561 of Ivanenkov. Ivanenkov discloses the alignment of 44 amino acids that result in the shorter length unique common motif of 8 amino acids, as shown in Table 1. Thus, even without the Kay reference, Ivanenkov already discloses, or at least suggests, the longer length 44 amino acid sequences from which the motif is derived.

In view of applicants' arguments the 103 rejection in view of Kraft is withdrawn.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 2-3, 13-14 and 17-56 drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T.D.
T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
August 25, 2005